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Ashley Smith — Ashley Smith
Name (Print) Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

WATANABE et al.

Application Number: 09/488,762

Filed: January 21, 2000

Art Unit: 1713

Examiner: Peter D. MULCAHY

#16 3/14/03

For: MEDICAL ADHESIVE TAPE OR SHEET, AND FIRST-AID ADHESIVE TAPE

REQUEST FOR REINSTATEMENT OF THE APPEAL

Assistant Commissioner for Patents
Washington, D.C. 20231

March 4, 2003

Sir:

A Brief on Appeal in the above-identified U.S. patent application was filed September 19, 2002 in response to the Examiner's final Office Action dated March 29, 2002. In response to the Brief on Appeal, the Examiner, though not officially saying that prosecution is reopened, did reopen prosecution with the issuance of a new non-final Office Action dated December 5, 2002. In the new Office Action, the Examiner maintained the previous rejection set forth in the final Office Action and issued two new rejections. In particular, the Examiner has now rejected claims 1-10 under 35 U.S.C. §103(a) and has rejected claims 1-10 in view of 35 U.S.C. §112, second paragraph. In the Supplemental Brief on Appeal submitted herewith, the Appellants have addressed these new rejections and further has repeated the previous arguments with respect to the original rejection set forth in the final Office Action dated March 29, 2002.

This Supplemental Appeal Brief complies with all requirements under 37 C.F.R. §1.192(c).

Accordingly, reinstatement of the Appeal is respectfully requested and the Board of Patent Appeals and Interferences is respectfully requested to consider the arguments set forth in the Brief on Appeal filed September 19, 2002 as well as this Supplemental Brief on Appeal filed with this

request. As set forth in M.P.E.P. §1208.02, since prosecution was reopened prior to a decision on the merits by the Board of Patent Appeals and Interferences, the fee paid for the Notice of Appeal and the Appeal Brief must be applied to this later Appeal regarding the same application. As indicated, when the Brief on Appeal was filed September 19, 2002 all fees were properly and timely paid. Accordingly, no fees are due at this time.

However, if there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,

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Reg. No. 33,251

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For: MEDICAL ADHESIVE TAPE OR SHEET, AND FIRST-AID ADHESIVE TAPE

SUPPLEMENTAL APPELLANTS BRIEF ON APPEAL

March 4, 2003

This is supplemental to the previous appeal to the Board of Patent Appeals and Interferences filed September 19, 2002, and now is in response to the Office Action dated December 5, 2002 which rejects claims 1-10 in the above-identified application. No claims stand allowed. The appealed claims are set forth in the attached Appendix.

I. THE REAL PARTIES IN INTEREST

The real party in interest, besides the named inventors, is the Nitto Denko Corporation of Osaka, Japan.

II. RELATED APPEALS AND INTERFERENCES

No other appeal or interference which will directly affect or be directly affected by or have a bearing on the Board's decision in this Appeal is known to the Appellants, or the Appellants' legal representative.

III. STATUS OF CLAIMS

The claims pending in the application are claims 1-10.

No claims have been added or cancelled throughout the course of this prosecution.

A copy of the claims on appeal can be found in the attached Appendix.

IV. STATUS OF AMENDMENTS

An Amendment After Final Rejection was submitted on June 21, 2002, but this amendment was not entered, as set forth in the Advisory Action dated July 9, 2002. In response to the Advisory Action dated July 9, 2002, Appellants submitted a brief dated September 19, 2002. In response, the Examiner issued an Office Action dated December 5, 2002 with two new rejections.

V. SUMMARY OF INVENTION

There is always a continuing effort to improve medical products, particularly those products relating to wound and surgical dressings. Conventional dressings have a number of drawbacks, ranging from the discomfort to the patient, to the environmental problems in disposing of various chlorinated compounds, as noted at page 2 of the present application.

The present invention involves a medical adhesive tape or sheet comprising a supporting substrate and an adhesive layer directly or indirectly laminated thereon, wherein the supporting substrate comprises a composition having 100 parts by weight of a thermoplastic resin and 10 to 200 parts by weight of a silicic acid compound, as is described at page 8 of the application.

The claimed invention contains a number of features that make it particularly desirable in the context of wounds and dressings. First, the claimed invention has a specific stress relaxation

ratio, as is described at page 23 of the application, and in the examples. The stress relaxation ratio is important in that medical dressings must remain attached to the skin of the user for considerable periods of time, requiring the ability to move and flex in order to accommodate the normal movements of the body. This is particularly important in the case of damaged skin or open wounds, where tension and compression may induce intense feelings of discomfort or pain in the user.

Second, as a result of the stretching process of the supporting substrate, a porous film can be generated, as is described at page 20. This film has high moisture permeability and therefore can "breath," as set forth at pages 20-21. These features make the film highly desirable in medical applications in which direct skin contact is necessary, since the comfort of the user is improved. The advantages of the present invention are demonstrated in greater detail in the numerous examples, for instance, at page 33 and Tables 1-6.

In summary, the specific stress relaxation ratio of the claimed invention and the direct application of the claimed invention to skin or wounds, are unique features of the claimed invention. As will be demonstrated below, these features are neither taught nor suggested in the cited art relied upon by the Examiner.

VI. ISSUES

The issues remaining for review by the Board of Patent Appeals and Interferences are:

A. The Examiner's rejection of claims 1-8 under 35 U.S.C. § 102(e) as being anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kobylivker et al. (U.S. Patent No. 6,002,064).

B. The Examiner's rejection of claims 1-10 under 35 U.S.C. § 103(a) as being

unpatentable over Kobylivker et al. taken in view of Joseph et al. (U.S. Patent No. 6,107,219), Hodgson (U.S. Patent No. 3,645,835) or Potter et al. (U.S. Patent No. 4,595,001).

C. The Examiner's rejection of claims 1-10 under 35 U.S.C. § 112, second paragraph, as being definite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

VII. GROUPING OF THE CLAIMS

As presently appealed, the groupings of the claims are as follows.

Claims 1-8 stand or fall together;

Claim 9 stands alone; and

Claim 10 stands alone.

VIII. ARGUMENTS

A. The Examiner's rejection of claims 1-8 under 35 U.S.C. § 102(e) as being anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kobylivker et al. (U.S. Patent No. 6,002,064).

i. The Examiner's rejection

At page 2 of the Office Action, the Examiner rejects claims 1-8 under 35 U.S.C. § 102(e), as anticipated by, or in the alternative, under 35 U.S.C. § 103(a), as obvious over Kobylivker et al. (U.S. Patent No. 6,002,064). The Examiner indicates that the rejection set forth in the Office Action dated March 29, 2002 (Paper No. 9), which refers to the Office Action dated October 4,

2001 (Paper No. 4), is repeated, and further indicates that the remarks of the appellants have been fully considered, but were not found to be persuasive. At page 2 of the first Office Action, the Examiner asserted that Kobylivker et al. shows a medical adhesive article incorporating a substrate comprised of the Appellants' thermoplastic resin and a silicic acid compound. The Examiner emphasized a few portions of the cited reference and concluded that the claims are not novel.

Then at page 3 of the first Office Action, the Examiner further stated that in the event that a person skilled in the art would not "immediately envisage" the claimed invention, the invention is obvious as well. More specifically, the Examiner stated that each of the ingredients is shown within the prior art and that one of ordinary skill would use these ingredients in combination with one another and in the specified amounts.

For the following reasons, the Examiner's rejection should be reversed.

ii. The Appellants' Reply to the Examiner's rejection of claims 1-8 under 35 U.S.C. § 102(e) as being anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kobylivker et al. (U.S. Patent No. 6,002,064).

a) The patentability of claims 1-8.

In terms of the claims at issue, the following summary is provided:

Claim 1 recites a medical adhesive tape or sheet comprising a supporting substrate and an adhesive layer directly or indirectly laminated thereon, wherein said supporting substrate comprises a composition which comprises 100 parts by weight of a thermoplastic resin and 10 to 200 parts by weight of a silicic acid compound.

Claim 2 is dependent on claim 1, and identifies specific silicic acid compounds.

Claims 3-5 are dependent claims that further define the characteristics of the thermoplastic resin.

Claim 6 is dependent on claim 1, and further defines the nature of the supporting substrate.

Claims 7-8 are dependent claims that further specify the features of the resin modifiers.

There are various significant differences between the Kobylivker et al. film and the claimed invention. As a starting point, one should note that the claimed invention is a medical adhesive tape or sheet. For such a device to adhere to a patient, it must have a specialized adhesive layer to promote attachment to the body, as is clearly set forth in claim 1. Moreover, for such an adhesive to work properly in health care applications, the adhesive must be pressure sensitive and capable of being removed without damaging the surface of a wound or other sensitive area. As anyone who has ever had a dressing removed from a wound can appreciate, the type of adhesive must be carefully chosen to provide enough adhesion to stick to the body, but the adhesive must also allow removal of the dressing without undue pain to the subject or damage to the skin.

By contrast, Kobylivker et al. shows an article that has a completely different structure and use. While the Examiner characterizes the Kobylivker et al. reference as teaching "medical adhesive articles," this conclusion is not supported in the patent. For instance, at column 2, lines 46-56 and column 9, lines 55-65, Kobylivker et al. indicates that the film may be useful for the manufacture of gowns, gloves, and other types of medical apparel. However, none of the cited text states or even suggests that the Kobylivker et al. article could be used as an adhesive tape or a sheet and be applied directly to a patient, which is a feature of the claimed invention.

The Examiner in a telephone conversation with Appellants' representative pointed to column 8, lines 45-50 of Kobylivker et al. as showing that an adhesive was present in the article described by that reference. The Examiner stated that the composition of the supporting substrate (a low crystallinity polypropylene polymer with a particulate filler) in Kobylivker et al. was very similar to the supporting substrate of the claimed invention, and that the differences in the adhesive were too small, in his view, to constitute a patentable difference.

With respect to the Examiner's argument concerning Kobylivker et al. showing the use of an adhesive, the particular paragraph referred to by the Examiner at column 8 of Kobylivker et al. is with respect to permanently bonding the film to one or more substrates. This is quite different from the adhesive layer on the substrate of the present invention. Particularly, at pages 23 and 24 of the present application, general classes of adhesives are discussed and it is clear that these adhesives are for purposes of temporarily adhering the medical adhesive tape or sheet to an object, such as a patient.

In addition, as the Board will appreciate, claim 1 and the claims dependent thereon recite a medical adhesive tape or sheet. This language in the claim at a minimum is preamble language and gives meaning to the claims as further shown in the present specification. As set forth in M.P.E.P. § 2111.02 which relates to the weight of a preamble, any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. Clearly, the terms "medical adhesive tape or sheet" would exclude the type of clothing set forth in Kobylivker et al. The term medical adhesive tape or sheet as set forth in the claims cannot be ignored or rendered generic by the Examiner. Clearly a medical adhesive tape or sheet is quite

different from the article of clothing only set forth in Kobylivker et al. Accordingly, based on this point alone, the rejections under § 102 and under § 103 should be reversed.

At page 3 of the Office Action, the Examiner responds to the previous arguments of the appellants. Although not specifically labeled as such, the Examiner divides his response into two parts, which are interrelated to some extent. His response deals with two topics: (i) structural differences; and (ii) the nature of the bonding.

The appellants respond to the two topics raised by the Examiner, in order, as follows:

First, as for the argument that there is a difference in structure between the "tape or sheet" as claimed, and the articles of Kobylivker et al., the Examiner states that the claim language is of such breadth so as to clearly be anticipated by the articles shown in Kobylivker et al. Additionally, the Examiner asserts that the medical adhesive tape of the claimed invention is not seen to be limited to a bandage or medical application device as is being argued by the applicants.

In response, the claims of the present invention are claiming a medical tape or sheet which does not encompass any clothing. For instance, the appellants do not believe that a laminate like a surgical gown can be easily characterized as a medical adhesive tape or sheet. A laminated surgical gown is simply not a medical adhesive tape or sheet in the normal meaning of those words. More particularly, the uses of Kobylivker et al. are strictly related to medical gowns, caps, aprons, and related apparel, which are quite different from first-aid adhesive tapes, and could not be substituted for those items. The Examiner does not dispute that only articles of clothing are shown in Kobylivker et al.

With respect to the Examiner's argument that the medical adhesive tape of the claimed

invention is not limited to a bandage or medical application device as argued by the applicants, the terms of a claim are given in their ordinary meaning to one skilled in the art. Furthermore, the general maxim of claim interpretation is that the claims must be read in light of the specification. The ordinary meaning of a medical adhesive tape or sheet is a tape or sheet used in medical uses particularly rolled bandage, surgical tape, plaster, poultice, dressing member, wound protector, and percutaneous absorption preparation. This meaning is fully supported in the specification at page 1 under the heading Field of the Invention. Furthermore, page 25 of the specification states that the medical adhesive tape or sheet of the claimed invention has less physical irritation to a skin even if adhered for a long period of time as well as good adhesiveness to a skin and feeling. Accordingly, the uses of the adhesive tape of Kobylivker et al. are quite different from the first-eight adhesive tapes of the claimed invention, and could not be substituted for those items.

Second, as for the argument that Kobylivker et al. is concerned with permanently bonding the film to substrates, and that the claimed invention is concerned with temporarily adhering the medical adhesive tape or sheet to a patient, the Examiner responds at some length. The Examiner states that the appellants are arguing limitations that are not claimed or reflected in the claims. The Examiner states that the claimed composition and the article resulting from the composition are anticipated by the reference. Therefore, the Examiner concludes that attempts to draw a distinction between the permanent coating or adhesive of Kobylivker et al. and the claimed invention are not persuasive.

In response, the appellants believe that the Examiner is not appreciating the fundamental structural differences between a medical tape and a gown. More specifically, the claimed invention is a removable article, because the adhesive layer is releasable in nature. A removable

article such as the claimed invention is completely different from the permanent laminates described in Kobylivker et al. Kobylivker et al. simply does not show a releasable adhesive. In fact, the types of applications shown in Kobylivker et al. would definitely not work if the adhesive was releasable. The Examiner's logic that an adhesive layer or medical adhesive tape is the same as laminates used to make clothing is not a position that one skilled in the art would take. These structural differences are inherent in the definitions of the respective items. Permanently laminating a layer to a substrate to form a garment is fundamentally different from medical tape removably attaching a layer to a living person or animal. Therefore, in view of the large differences in structure and potential uses between the claimed invention and the article shown in Kobylivker et al., it is clear that Kobylivker et al. does not and cannot anticipate the claimed invention.

Accordingly, in light of all the reasons set forth above, Kobylivker et al. does not anticipate the claimed invention, and the rejection of claims 1-8 should be reversed.

As for the obviousness issue, the Examiner has previously stated that each of the ingredients is shown within the prior art, and that one of ordinary skill would use these ingredients in combination with one another and in the specified amounts to produce the claimed invention. This is simply not true, for the various reasons set forth below. For instance, this analysis assumes that the adhesive used in the claimed invention is an obvious variant of the adhesive used in Kobylivker et al.

While there are various portions of the cited patent where adhesives are mentioned, such as at column 2, lines 46-49, column 8, lines 46-49, or column 9, lines 35-55, these portions all refer to permanently bonding a film layer to some sort of substrate to form an article. Therefore,

any use of Kobylivker et al. as a starting point could not lead to the claimed invention. The claimed invention is not designed to permanently bound two substrates or layers together, because the adhesive used in the claimed invention is not, and cannot be, a permanent adhesive.

Adhesives vary greatly; this is why there are literally hundreds, if not thousands, of different adhesives known. The properties that make an adhesive suitable for one application may make it unsuitable for a different application. This is especially true in the present context. An adhesive that permanently bonds a tape or dressing to a person's skin, particularly the sort of sensitive or damaged skin found in surgical wounds, might possibly be disastrous in patient care applications. A permanent adhesive is completely different from the pressure sensitive adhesive layer of the present invention, in which a relevant characteristic of the adhesive concerns its removability from skin.

At pages 23 and 24 of the present application, the general classes of adhesives used in the claimed invention are discussed in detail. These adhesives are for purposes of temporarily adhering the medical adhesive tape or sheet to a person, such as a patient. Accordingly, the adhesives of the claimed invention cannot be irritating to skin, which is why the acrylic adhesives are especially preferred, as set forth at page 23, fourth full paragraph.

Additionally, the examples, such as Tables 7 and 8, and the accompanying text at pages 32 and 33, show the test properties of the claimed invention and further illustrate that the claimed invention is not permanently bonded to the skin, i.e., that the adhesive is releasable in nature, and that the invention is removable once applied to human skin. For instance, in the final paragraph of page 32 of the application, there is an express recitation that the patches of the claimed

invention were applied to subjects for a period of 24 hours, confirming that the adhesive is indeed releasable.

Therefore, in light of the text cited above, it is clear that the adhesive layer is used in the claims and in view of the specification is of a releasable nature. No similar considerations of removability or non-irritation are discussed in Kobylivker et al., nor would the permanent laminations discussed in that reference lead a person skilled in the art to substitute an adhesive having different properties. The fact that a permanent adhesive is used is unequivocal evidence that the Kobylivker et al. is confined to applications in which the film is permanently bound to another structure. In such applications, removability is an extremely undesirable characteristic, and the main focus of lamination operations is ensuring that once two layers are bonded together, they never delaminate. Permanent adhesives of the type useful in lamination operations naturally lead away from any consideration of a removable adhesive or any application based on removable adhesives. For this reason, a person skilled in the art in possession of the Kobylivker et al. reference could not change the nature of the adhesive unless he had an intention to create a totally different invention, i.e., a medical adhesive tape that could be applied directly to human skin and removed later. However, such an article is not found or suggested in Kobylivker et al., and therefore it must only arise through the improper use of hindsight.

Therefore, the physical characteristics of the adhesive layer will vary depending on the type of the adhesive, specifically whether the adhesive is used to releasably attach a film to the skin, or permanently adhere the film to a substrate in order to create a laminate. This is another reason why the teachings of Kobylivker et al. lead away from the claimed invention and could not be used to generate the claimed invention.

In summary, the benefits achieved and discussed in the present application with respect to a specialized pressure sensitive adhesive as well as the other benefits mentioned in the examples, would not be relevant to the uses specified in Kobylivker et al. Therefore, these particular benefits would not be obvious in view of Kobylivker et al., nor would one skilled in the art be motivated to use a polymeric film of Kobylivker et al. for the particular uses set forth in the present application, namely a first-aid adhesive tape. The particular medical adhesive tape including the adhesive layer are simply not the articles or uses of the articles taught or suggested by Kobylivker et al., since Kobylivker et al. was not concerned with the particular problems solved by the present application.

Accordingly, in light of all the above, Kobylivker et al. does not teach or suggest the claimed invention, and the rejection of claims 1-8 should be reversed.

B. The Examiner's rejection of claims 1-10 under 35 U.S.C. § 103(a) as being unpatentable over Kobylivker et al. taken in view of Joseph et al. (U.S. Patent No. 6,107,219), Hodgson (U.S. Patent No. 3,645,835), or Potter et al. (U.S. Patent No. 4,595,001).

i. The Examiner's rejection

At page 3 of the Office Action, the Examiner rejects claims 1-10 under 35 U.S.C. § 103(a) as being unpatentable over Kobylivker et al. taken in view of Joseph et al. (U.S. Patent No. 6,107,219), Hodgson (U.S. Patent No. 3,645,835), or Potter et al. (U.S. Patent No. 4,595,001). The Examiner asserts that the Kobylivker et al. patent clearly shows the claimed substrate comprised of the thermoplastic resin and the silicic acid compound. Specifically, the Examiner asserts that Kobylivker et al. is directed to medical laminates that are formulated into

sheets and is not at all limited to the end use of the sheet product disclosed. The Examiner then asserts that the secondary references are directed to bandage applications which incorporate a substrate and an external adhesive layer. According to the Examiner, these patents further incorporate thermoplastic resin substrates as well as laminates that are useful in the medical tape and bandaging arts. The Examiner maintains that it would be prima facie obvious to utilize the laminate, as shown in Kobylivker et al., in a medical tape or bandage application as shown in the secondary references, given that one of ordinary skill in the art would readily appreciate its end use potential in such applications. Therefore, the Examiner concludes that nothing in Kobylivker et al. would exclude such bandaging and/or medical tape applications.

For the following reasons, the Examiner's rejection should be reversed.

ii. The Appellants' Reply to the Examiner's rejection of claims 1-10 under 35 U.S.C. § 103(a) as being unpatentable over Kobylivker et al. taken in view of Joseph et al. (U.S. Patent No. 6,107,219), Hodgson (U.S. Patent No. 3,645,835), or Potter et al. (U.S. Patent No. 4,595,001).

a) The patentability of claims 1-8.

As stated above, Kobylivker et al. does not teach or suggest the claimed invention. In summary, Kobylivker et al. shows an article that has a completely different structure and use. Kobylivker et al. indicates that the film may be used for the manufacture of gowns, gloves, and other types of medical apparel. Additionally, Kobylivker et al. uses an adhesive that permanently bonds a film to one or more substrates. Thus, Kobylivker et al. teaches away from the use of the adhesive for purposes of temporarily adhering the medical adhesive tape to a patient, or a releasable adhesive tape to a removable article. Kobylivker et al., which shows permanently

laminating a layer to a substrate to form a garment, is fundamentally different from a medical tape removably attaching a layer to a living person or animal. No consideration of removability or non-irritation is discussed in Kobylivker et al., nor would the permanent laminations discussed in that reference lead a person skilled in the art to substitute an adhesive having different properties. The use of a permanent adhesive is unequivocal evidence that the Kobylivker et al. is confined to applications in which the film is permanently bound to another structure. In such applications, removability is an extremely undesirable characteristic.

Joseph et al. relates to pressure-sensitive adhesive coated breathable non-woven tape backing substrate where the non-woven tape backing comprises a fibrous non-woven web formed, in part, by multi-component fibers having an adhesive component region. According to Joseph et al., the adhesive component region is preferably a pressure-sensitive adhesive region formed by hot melt co-extrusion of at least two components to form the multi-component fibers. Column 4, lines 7-14 of Joseph et al. indicates that the multi-component fibers can be mixed with other fibers in the backing, such as other melt spun fibers, staple fibers, including inorganic and organic fibers, such as thermoplastic fibers, carbon fibers, glass fibers, mineral fibers, or organic binder fibers, as well as fibers of the different polymers. The pressure-sensitive adhesive fibers of Joseph et al. can be mixed with particulates, such as sorbent particulate material, fumed silica, and the like. At column 6, lines 30-35, Joseph et al. states that the tackifier portion of the pressure-sensitive adhesive generally comprises from 20 to 300 parts per 100 parts of the elastomer phase. Furthermore, at column 10, lines 24-35, Joseph et al. states that suitable non-adhesive materials are for use in forming conjugate multi-component fibers, for use in blends with the pressure-sensitive adhesive, or for use as separate fibers, include polyolefins, polyurethanes, polyesters, polyalkylenes,

polyamides, polystyrenes, polyarylsulfones, or polydienes. These materials are preferably extensible or slightly elastomeric, but could be elastomeric. According to Joseph et al., extensible or slightly elastomeric polyurethanes, and polyurethanes, such as polypropylenes are preferred.

The adhesive tape of Joseph et al. is designed to adhere to a surface that is a source of moisture such as skin; therefore, one skilled in the art would not combine Joseph et al. with Kobylivker et al. Additionally, the fumed silica in Joseph et al. is incorporated into the adhesive layer, while the silicic acid compound of the present invention is incorporated into the supporting substrate. Silicic acid in the supporting substrate improves the heat resistance and moldability of the substrate. Accordingly, heat treatment at higher temperatures becomes possible and the production rate increases, which lowers the production costs. The fumed silica in the adhesive layer of Joseph et al. does not provide any advantages. In fact, the only apparent purpose of the fumed silicas in Joseph et al. is to act as a filler. Also, Joseph et al. does not teach or suggest the amount of the fumed silica in the adhesive layer. Furthermore, Joseph et al. does not teach or suggest the amount of elastomer in the backing substrate. In fact, Joseph et al. only states that the tackifer portion of the pressure-sensitive adhesive includes 20 to 300 parts per 100 parts of the elastomer phase. Therefore, the combination of Joseph et al. with Kobylivker et al. does not teach or suggest the claimed invention.

With respect to Hodgson, Hodgson relates to a moisture-vapor-permeable pressure-sensitive adhesive material for use on animal skin and nails. According to Hodgson, the backing material is a microporous film of plasticized polyvinyl chloride or non-woven fabric. Additionally, the adhesive material is a polyvinyl ethyl ether or an acrylic ester copolymer containing hydrophilic groups. Hodgson does not teach or suggest that the supporting substrate includes a composition

which comprises 100 parts by weight of a thermoplastic resin and 10-200 parts by weight of a silicic acid compound. Furthermore, Hodgson relates to adhesive tape designed to adhere to a surface such as animal skin; therefore, one skilled in the art would not combine Hodgson with Kobylivker et al. which relates to permanently laminating a layer to a substrate to form a garment that is fundamentally different from pressure-sensitive adhesive material for use on animal skin and nails.

With respect to Potter et al., Potter et al. relates to surgical dressing which consist essentially of a film which carries an adhesive layer for securing the dressing to the body characterized in that the film is continuous and comprises a polymer which when in contact with water has a higher MVP than when in contact with moisture vapor, but not water. Additionally, the adhesive layer in Potter et al. is adapted to allow access of water to the film when water is in contact with the adhesive layer. Potter et al. does not teach or suggest that the supporting substrate includes 100 parts by weight of a thermoplastic resin and 10-200 parts by weight of a silicic acid compound. Additionally, because Potter et al. relates to surgical dressing designed to adhere to the body, one skilled in the art would not combine Potter et al. with Kobylivker et al.

Accordingly, as stated above, Joseph et al., Hodgson, and Potter et al. relate to surgical dressings designed to adhere to the body, while Kobylivker et al. relates to garments; therefore, one skilled in the art would not combine the secondary references with Kobylivker et al. Furthermore, even the combinations of the references do not teach or suggest the claimed invention, and the rejection of claims 1-8 should be reversed.

b) The patentability of claim 9.

Claim 9 is a product claim that is dependent on the medical adhesive tape or sheet of claim 1. Claim 9 further recites that the supporting substrate has a stress relaxation ratio of 60% or less.

The reasons set forth above with respect to the patentability of claims 1-8 apply equally here. Further, it is clear that the stress relaxation ratios set forth at page 23, first full paragraph, and claim 9 of the application, are an important embodiment of the claimed invention, and are not shown or suggested by Kobylivker et al. When a medical adhesive tape is attached directly to skin, particularly skin that is sensitive or damaged, it is clear that the flexibility is an extremely desirable quality. Although a medical garment may be in close contact with skin, it does not need to match every contour of the skin or respond to every movement of the body to function well. By contrast, a medical adhesive tape that is adhered directly to the skin preferably matches all of the contours of the skin and is able to accommodate movement of the body in order to perform its intended function.

In other words, the ability of the medical adhesive tape to flex or deform is an important characteristic of the claimed invention and is intimately related to both the comfort of the user and the ability of the tape to adhere to the skin in spite of body movements. A person in possession of Kobylivker et al. would have no reason to seek the particular stress relaxation ratios of the claimed invention, because they are utterly unrelated to the applications shown in Kobylivker et al., in which flexibility is not an important consideration. Therefore, a person of ordinary skill in the art in possession of the teachings of Kobylivker et al. would not be able to generate the claimed invention using that reference as a starting point.

As stated previously, Joseph et al. relates to adhesive tape designed to adhere to a surface that is a source of moisture, such as skin. Additionally, Joseph et al. at table 1 shows different

backing samples having tensile strengths ranging from 3242 g/2.5 cm to 1802 g/2.5 cm. However, nowhere does Joseph et al. teach or suggest a supporting substrate that includes a stress relaxation ratio of 60% or less. The tensile strengths mentioned in Joseph et al. do not correlate to a support substrate that has a stress relaxation ratio of 60% or less. In fact, there is no discussion regarding a strength relaxation ratio in Joseph et al.

As stated above, Hodgson relates to a moisture-vapor-permeable pressure-sensitive adhesive material for use on animal skin and nails. Hodgson at column 4, lines 25-70, provides a list of continuous backing material. However, Hodgson does not teach or suggest a stress relaxation ratio of 60% or less. In fact, Hodgson does not provide any information about a stress relaxation ratio.

As stated previously, Potter et al. relates to surgical dressing which consists essentially of film which carries an adhesive layer for securing the dressing to the body characterized in that the film is continuous and comprises a polymer. Potter et al. does not teach or suggest a substrate having a stress relaxation ratio of 60% or less. In fact, no discussion regarding a stress relaxation ratio or a tensile stress exists in Potter et al.

In summary, the benefits achieved and discussed in the present application with respect to a specialized pressure-sensitive adhesive, the unique stress relaxation ratios, as well as the other benefits mentioned in the examples, would not be relevant to the uses specified in Kobylivker et al. Therefore, these particular benefits would not be obvious in view of Kobylivker et al., nor would one skilled in the art be motivated to use a polymeric film of Kobylivker et al. for the particular uses set forth in the present application, namely a first-aid adhesive tape. The particular medical adhesive tape including the adhesive layer are simply not the articles or uses of

the articles taught or suggested by Kobylivker et al., since Kobylivker et al. was not concerned with the particular problems solved by the present application. Additionally, because Kobylivker et al. does not relate to medical adhesive tapes, one skilled in the art would not combine Kobylivker et al. with Joseph et al., Hodgson, or Potter et al.

Accordingly, for the reasons stated above, Kobylivker et al. in view of Joseph et al., Hodgson, or Potter et al. does not teach or suggest the claimed invention, and the rejection of claim 9 should be reversed.

c) The patentability of claim 10.

Claim 10 is a product claim that is dependent on the medical adhesive tape or sheet of claim 1. Claim 10 adds the feature that an absorbent pad is provided at a central region of the adhesive layer, to produce a first-aid adhesive tape.

The reasons set forth above with respect to the patentability of claims 1-8 apply equally here. Further, Kobylivker et al. does not teach or suggest a first-aid tape with an absorbent pad, because Kobylivker et al. is not concerned with applying a medical adhesive tape or sheet to skin. Obviously, the types of applications that are set forth in Kobylivker et al. would not contain an absorbent pad, because Kobylivker et al. is concerned with completely different types of articles, i.e., articles that are not attached to skin to serve as a dressing or a first aid tape. In summary, the Examiner has not explained how a person skilled in the art could generate the features of this claim when an absorbent pad is neither taught nor suggested by Kobylivker et al. and when an absorbent pad would be inconsistent with the kinds of medical apparel taught by Kobylivker et al.

Joseph et al. does not teach or suggest a first-aid tape with an absorbent pad provided at a central region on a surface of an adhesive layer. Joseph et al. concerns a pressure-sensitive adhesive-coated breathable non-woven tape backing substrate where the non-woven tape backing comprises a fibrous non-woven web formed in part by multi-component fibers having an adhesive component region. According to Joseph et al., the adhesive tape can adhere to a surface that is a source of moisture, such as skin. However, Joseph et al. does not teach or suggest an absorbent pad provided at a central region on a surface of an adhesive layer. Furthermore, Joseph et al. does not teach or suggest a composition which comprises 100 parts by weight of a thermoplastic resin and 10 to 200 parts by weight of a silicic acid compound.

With respect to Hodgson, Hodgson relates to a moisture-vapor-premeable pressure-sensitive adhesive material for use on animal skin and nails. According to Fig. 5 of Hodgson, a dressing pad 18 is situated roughly centrally of the dressing on the adhesive side. A protector is provided to cover the pad and adhesive. The protector is removed when the dressing is required for use. However, Hodgson does not teach or suggest that the dressing pad is made from an absorbent material. Furthermore, Hodgson does not teach or suggest a composition which comprises 100 parts by weight of a thermoplastic resin and 10 to 200 parts by weight of a silicic acid compound.

Potter et al. also relates to a surgical dressing which consists essentially of a film carrying an adhesive layer for securing the dressing to the body. This dressing is characterized in that the film is continuous. However, Potter et al. does not teach or suggest an absorbent pad provided at a central region on a surface of the adhesive layer. In fact, there is no mention of any type of padding on a surface of an adhesive layer in Potter et al. Furthermore, Potter et al. does not teach or suggest a composition which comprises 100 parts by weight of a thermoplastic resin and 10 to 200 parts by

weight of a silicic acid compound. In summary, Joseph et al., Hodgson, and Potter et al. all relate to a material for use on animal skin. However, Kobylivker et al. relates to adhesive material in garments. Accordingly, one skilled in the art would not combine Kobylivker et al. with Joseph et al., Hodgson, or Potter et al. Furthermore, the combination of Kobylivker et al. with Joseph et al., Hodgson, and Potter et al. does not teach or suggest the claimed invention, and therefore the rejection of claim 10 should be reversed.

C. The Examiner's rejection of claims 1-10 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

i. The Examiner's rejection.

At page 5 of the Office Action, the Examiner rejects claims 1-10 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. According to the Examiner, the applicants' recitation of "directly or indirectly laminated thereon" in the claims is indefinite. According to the Examiner, it is unclear how this further limits the claim. Furthermore, the Examiner asserts that it is unclear whether the adhesive is applied to form a layer which is either directly attached to the substrate layer or to an intermediate layer between the substrate layer and the adhesive layer or the language intended to limit the method of the application of the adhesive. According to the Examiner, Kobylivker et al., at column 9, lines 35+, shows many methods for forming laminates and applying an adhesive layer to the sheet material. As such, the Examiner asserts that it is unclear what or how an indirect versus direct method of application limits the claimed invention.

For the following reasons, the Examiner's rejection should be reversed.

ii. The Appellants' Reply to the Examiner's rejection of claims 1-10 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly to point out and distinctly claim the subject matter which applicants regard as the invention.

a) The patentability of claims 1-8.

With respect to the expression "directly or indirectly laminated thereon," one skilled in the art would clearly understand the expression to convey that the adhesive layer can either be directly attached to the supporting substrate or that there can be an intermediate layer between the substrate layer or the adhesive layer. This expression is fully supported in the last paragraph at page 4 and the fourth paragraph at page 8 of the specification. Therefore, one skilled in the art would clearly understand the language of the claim.

In addition, the Examiner clearly understood this expression during the entire pendency of this application. Since 2001, the Examiner was aware of this language, examined based on this language and issued multiple Office Actions without questioning this language. It is clear by the Examiner's previous actions that the language is quite clear to all.

Accordingly, for the reasons stated above, the expression directly or indirectly laminated thereon is definite, and the rejection of claim 1-8 should be reversed.

b) The patentability of claim 9.

Claim 9 is dependent on claim 1; therefore, the reasons set forth above with respect to the patentability of claims 1-8 apply equally here. Claim 9 does not directly recite the expression "directly or indirectly laminated thereon"; however, claim 9 is dependent on claim 1 which recites the express "directly or indirectly laminated thereon."

As stated earlier, one skilled in the art would clearly understand that the expression "directly or indirectly laminated thereon," indicates that the adhesive layer can either be directly attached to the supporting substrate or there can be an intermediate layer between the substrate layer or the adhesive layer. The expression "directly or indirectly laminated thereon," is further supported at pages 4 and 8 of the specification.

Accordingly, the expression "directly or indirectly laminated thereon," is definite, and therefore the rejection of claim 9 should be reversed.

c) The patentability of claim 10.

Claim 10 is dependent on claim 1; therefore, the reasons set forth above with respect to the patentability of claims 1-8 apply equally here. Claim 10 does not directly recite the expression "directly or indirectly laminated thereon"; however, claim 10 is dependent on claim 1 which recites the express "directly or indirectly laminated thereon."

As stated earlier, one skilled in the art would clearly understand that the expression "directly or indirectly laminated thereon," indicates that the adhesive layer can either be directly attached to the supporting substrate or that there can be an intermediate layer between the substrate layer or the adhesive layer. The expression "directly or indirectly laminated thereon," is further supported at pages 4 and 8 of the specification.

Accordingly, the expression "directly or indirectly laminated thereon," is definite, and therefore the rejection of claim 10 should be reversed.

IX. CONCLUSION

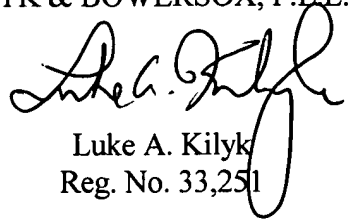
For at least the reasons discussed above, it is respectfully submitted that the Examiner's

rejection of all the pending claims is in error and should be reversed.

If there is any additional fee due in connection with the filing of this Brief on Appeal, please charge the fee to Deposit Account No. 50-0925.

Respectfully submitted,

KILYK & BOWERSOX, P.L.L.C.



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